

I hereby certify that on 5/18/04, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450.

Morio Nodol

Applicant: Robin C. Whitmore

Serial No.: 10/624,735 Filed: 07/21/2003

Title: SELF-DRILLING, SELF-

TAPPING BONE SCREW

Examiner: David C. Comstock

Group Art Unit: 3733

Docket No.: 53977-00001 (formerly

CRANIO-42318)

Confirmation No.: 7156

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PETITION UNDER 37 C.F.R. §1.91 TO ACCEPT AN EXHIBIT

Mail Stop Amendment P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants hereby petition under 37 C.F.R. §1.91 to accept exhibits as part of the response to the Office Action mailed January 10, 2006.

The Examiner has rejected the claims of the instant application over prior art screws not having the generally flat cutting tip of the claimed invention. Applicants believe that photographs of the cutting tip of the claimed bone screw will assist the Examiner in the examination of the pending claims of the instant application. Applicants therefore enclose Exhibits 1-3 comprising photographs of the claimed invention and a declaration from inventor Robin C. Whitmore asserting that the bone screw depicted in the photographs is the claimed bone screw.

Applicants submit herewith the fee under 37 C.F.R. §1.17(h) of \$130.00 for this petition.

The Commissioner is authorized to charge any additional fees required in connection with this petition and the application above to Deposit Account No. 50-3207.

Respectfully submitted,

Date: 5/18/06

Michelle Sescribists No. 54 22

Registration No.4654,124

130.00 OP

PRESTON GATES & ELLIS LLP

1900 Main Street, Suite 600 Irvine, California 92614-7319 Telephone: 949.253-0900

Facsimile: 949.253-0902

I hereby certify that on this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450.

Jaria Nadal

PATENT

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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

# **DECLARATION OF FACTS IN SUPPORT OF EXHIBITS SUBMITTED UNDER 37 CFR §1.91**

Mail Stop Amendment **Commissioner of Patents** Washington, D.C. 20231

Sir:

This Declaration is made in support of the exhibits submitted under 37 CFR §1.91 along with a Response to Final Office Action and Request for Continued Examination.

I am an inventor of the above-referenced application.

I have read and understood the Office Action mailed and January 10, 2006 and the response thereto.

I personally photographed the claimed self-drilling bone screw to generate the photographs in Exhibits 1-3 enclosed herein. The photographs depict the bone screw as graphically depicted in Figures 1 and 2 and on page 3, line 28 to page 4, line 2 of the application, as filed.

No new matter is included in the photographs.

#### **EXHIBITS**

Exhibit 1. Photograph of self-drilling bone screw disclosed and claimed in U.S. Patent Application No. 10/624,735 at approximately 15x magnification.

May. 18 2006 12:58PM P2

FAX NO. :805-582-4935

FROM:

Appl. No.: 10/624,735

Art Unit: 3733

Patent 53977-00001

Exhibit 2. Photograph of the flat cutting tip of self-drilling bone screw disclosed and claimed in U.S. Patent Application No. 10/624,735 at approximately 26x magnification.

Exhibit 3. Photograph of the flat cutting tip of self-drilling bone screw disclosed and claimed in U.S. Patent Application No. 10/624,735 at approximately 40x magnification.

### STATEMENT BY INVENTOR

- 1. Claims 1-16 of U.S. Patent Application No. 10/624,735 have been rejected under 35 USC §103(a) as being unpatentable over Okada *et al.* (U.S. Patent No. 4,323,326) in view of Schwartzman *et al.* (U.S. Patent No. 4,125,050).
- 2. The Exhibits comprise photographs of the bone screw which demonstrate the differences between the claims bone screw and the prior art cited by the Examiner.
- 3. Okada et al. describes a self-drilling screw comprising a body having a head at one end and a tip at the other end, and dual lead threads. Okada et al. do not disclose a single flat cutting edge extending generally perpendicular to a central longitudinal axis of the body. Figures 1A, 1B, 3 and 5 of Okada et al. depict a self-drilling screw with a pointed cutting tip generated at the intersection of end faces 8 and 9. Figure 1 of the instant application and Exhibits 2 and 3 demonstrate that the claimed self-drilling bone screw has a flat cutting edge.
- 4. Schwartzman et al. describes in the abstract and in Figure 3 a self-drilling screw formed with longitudinally extending flutes located substantially on opposite sites of the body, these flutes defining rectilinear tip and side cutting edges positioned along opposite sides of the body, the tip cutting edges being forwardly offset and angularly diverging from the ends of a transverse cutting edge, formed on a tip web. As can be seen in Figure 3 of Schwartzman et al., the prior art screw does not have a flat cutting edge. Figure 1 of the instant application and Exhibits 2 and 3 clearly depict a flat cutting edge which is perpendicular to the central longitudinal axis of the body of the screw.
- 5. Based upon my reading of the prior art, the self-drilling screws described in the cited prior art, Okada *et al.* and Schwartzman *et al.*, do not have all the features of the self-drilling bone screw I claimed in U.S. Patent Application No. 10/624,735.

Appl. No.: 10/624,735

Art Unit: 3733

Patent 53977-00001

# ACKNOWLEDGEMENT UNDER 18 U.S.C. §1001

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such statements may jeopardize the validity of the application or any patent issued thereon.

IN TESTIMONY WHEREOF, I hereunder set my hand this 18th day of May 2006

Robin C. Whitmore

STATE OF

COUNTY OF

On 5-18-06

before me,

SS

Notary Public, personally appeared Robin C, Whitmore, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal

SIGNATURE OF NOTARY PUBLIC

I. FRIEDMAN
Commission # 1505704
Notary Public - Colifornia
Ventura County
My Comm. Expires Aug 31, 2008

PTO/SB/17p (11-04)

Approved for use through 07/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE aperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# **PETITION FEE** Under 37 CFR 1.17(f), (g) & (h) TRANSMITTAL

(Fees are subject to annual revision)

Send completed form to: Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450

Application Number	10/624,735
Filing Date	07/21/2003
	Robin C. Whitmore
Art Unit	3733
Examiner Name	David C. Comstock
Attorney Docket Number	53977-00001 (CRANIO-42318)

Enclosed is a petition filed under 37 CFR 1.91 that requires a processing fee (37 CFR 1.17(f), (g), or (h)). Payment of \$ 130.00 is enclosed.  This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. For transmittal of processing fees under 37 CFR 1.17(i), see form PTO/SB/17i.
Payment of Fees (small entity amounts are NOT available for the petition fees)  The Commissioner is hereby authorized to charge the following fees to Deposit Account No:  petition fee under 37 CFR 1.17(f), (g) or (h) any deficiency of fees and credit of any overpayments Enclose a duplicative copy of this form for fee processing.
Check in the amount of \$ 130 · 60 is enclosed.  Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.
Petition Fees under 37 CFR 1.17(f): Fee \$400 Fee Code 1462 For petitions filed under:  § 1.53(e) - to accord a filing date.  § 1.57(a) - to accord a filing date.  § 1.182 - for decision on a question not specifically provided for.  § 1.183 - to suspend the rules.  § 1.378(e) - for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.  § 1.741(b) - to accord a filing date to an application under § 1.740 for extension of a patent term.
Petition Fees under 37 CFR 1.17(g): Fee \$200 Fee Code 1463  For petitions filed under:  § 1.12 - for access to an assignment record.  § 1.14 - for access to an application.  § 1.59 - for expungement of information.  § 1.103(a) - to suspend action in an application.  § 1.136(b) - for review of a request for extension of time when the provisions of section 1.136(a) are not available.  § 1.295 - for review of refusal to publish a statutory invention registration.  § 1.377 - for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.  § 1.550(c) - for patent owner requests for extension of time in expante reexamination proceedings.  § 1.956 - for patent owner requests for extension of time in inter partes reexamination proceedings.  § 5.12 - for expedited handling of a foreign filing license.  § 5.25 - for retroactive license.
Petition Fees under 37 CFR 1.17(h): Fee \$130 Fee Code 1464 For petitions filed under:  § 1.19(g) - to request documents in a form other than that provided in this part.  § 1.84 - for accepting color drawings or photographs.  § 1.91 - for entry of a model or exhibit.  § 1.102(d) - to make an application special.  § 1.138(c) - to expressly abandon an application to avoid publication.  § 1.313 - to withdraw an application from issue.  § 1.314 - to defer issuance of a patent.
Muchelle Stades 5/18/06 Signature Date
Michelle S. Glasky  54,124  Typed or printed name  Registration No., if applicable
Typed or printed name Registration No., if applicable

This collection of information is required by 37 CFR 1.17. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.